

**Remarks**

Applicants request entry of the present amendment in the cited application. When this amendment is entered, claim 1 (amended), and dependent claims 2-9, 13 (amended), 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 are pending. Reconsideration of the application is requested.

The present remarks are filed in response to the office action mailed July 19, 2006. This office action is an action on the merits in view of the grant of the request for continued examination filed April 26, 2006. Applicants thank the Examiner for indicating that the submission filed on April 26, 2006, amending claim 1, has been entered in this application.

Applicants note the office action indicates that the Information Disclosure Statement filed May 11, 2006 was not considered because that IDS may have failed to list a date and place of publication for each cited document. For clarification, the documents that were filed with the IDS filed May 11, 2006 are papers or English translations of papers filed in an on-going opposition proceeding for the related granted European patent 1 196 243 (originally filed July 7, 2000 with European Patent Office). Since opposition proceedings before the European Patent Office are open proceedings, all of the documents associated with this opposition are publicly available and are relevant because of the corresponding subject matter between the pending US application and the granted European application. If there is any confusion about the relevant dates of the cited documents, Applicants submit that the availability of the documents is clearly identifiable by the dates set out on the face of each of the documents. Applicants request that the attached IDS that is re-submitted in this case be entered without any additional fee. But if a further fee is necessary, the Examiner is requested to charge that fee to Deposit Account 06-0029.

Applicants submit that the amendment to claims 1 and 13 are supported by the original specification and claims. No new matter is added to the application. In particular, Applicants point out that the phrase "fluid control film" recited in amended claim 1 is defined in the specification at page 10 as referring to a film having a surface comprising a "microreplicated pattern." Fluid control films having precisely replicated channels in predetermined patterns

include the embossed thermoplastic materials set out in the specification at page 11, lines 14-24. In addition, the Examples at pages 52-67 disclose various embodiments of films that have embossed microchannels on a surface of the film. Applicants also point out that alternative embodiments for modifying a surface of a fluid control film as now recited in amended claim 13 are set out in the specification at page 19, line 27 bridging to page 21, line 9.

In the outstanding office action, all of the pending claims were rejected under 35 USC 112, second paragraph, as being indefinite. For completeness, Applicants note that part of the listing of pending claims set out in the office action is incorrect, i.e, claims 1-9 (not 1-19) are pending, and claim 42 is not pending because it had been previously cancelled. The other listed pending claims are correct.

In rejecting independent claim 1 as being indefinite, the Examiner has specifically noted that the phrase "uniform and regular" in reference to the length of the microchannels is not defined or exemplified anywhere. Further, the Examiner has stated that Merriam-Webster defines "uniform and regular" to mean "presenting an unvaried appearance of surface, pattern or color" and "having always the same form, manner or degree; not varying or variable." Further the Examiner stated that "uniform" may mean "formed ...according to some established ...type" but that no 'rule' for forming channels is disclosed, and the channels are disclosed to be of varying size, heights and widths."

Applicants submit that the specification, taken as whole, clearly describes uniform and regular microchannels and that this description is consistent with the dictionary definitions that are identified by the Examiner. In particular, claim 1, as amended, recites that at least one major surface of a polymeric fluid control film contains a plurality of embossed microchannels. Stated another way, the microchannels are formed on the surface of the film by an embossing process. As set out in the specification at page 11, lines 14-24, channels that are "precisely replicated, with high fidelity from a predetermined pattern" may be formed from a thermoplastic material suitable for embossing. Those of ordinary skill would readily ascertain that an embossing process would impart a uniform and regular pattern on the film's surface where the predetermined pattern is established by an embossing tool. Although different embossing tools, as contemplated by alternative embodiments of the present invention, might provide differently sized or shaped

microchannels, the major surface of any particular film would certainly have embossed channels that have patterns provided by the embossing tool and that would be "uniform and regular" along substantially each channel length. Applicants submit that a pattern of embossed microchannels on the surface of a film would be understood by the skilled person to be "uniform and regular."

Applicants also submit that embossed microchannels formed by an embossing process provides a "rule" for understanding the meaning of microchannels that are uniform and regular along substantially each channel length. Briefly, the "rule" is in part a predetermined pattern on an embossing tool and then the predetermined pattern on the embossing tool is used to create a precisely replicated, uniform and regular microchannel on the surface of a film. Again, Applicants submit that the skilled person would understand that this "rule" or process would provide uniform and regular channels along substantially each channel length.

Applicants further submit that these precisely replicated microchannels, once formed and included on the surface of the film, would not be substantially changed when the surface of the film is divided into different regions or zones, such as the acquisition and detection zones currently recited in claim 1. Although the Examiner has argued that it is unclear what combination of limitations is actually intended in claims 2 and 3, Applicants submit that different zones along the length of the channels does not make claims 2 and 3 unclear. Since the structure of the surface of the film is created by the embossing process, the regular and uniform pattern or shape of the embossed microchannels themselves are not changed by dividing the film surface into different zones. In addition, when other features are associated with different zones, such as the apertures and/or notches noted by the Examiner, these features do not change the overall regular and uniform pattern or shape of the embossed microchannels on the surface of the film. Similarly, adding elements or structures, such as detection elements, into the microchannels also does not change the overall regular and uniform pattern or shape of the embossed microchannels. These additional elements or structures may change the flow characteristics of a fluid through or along the channel, but the surface of the film containing the channels is not changed. In other words, changes that may occur to fluids along the path of the channel in different regions of the claimed detection article do not change the structure of the channel per se because the channel structure is associated with the embossing formation process.

For at least the reasons listed above, Applicants submit that claim 1, as well as claims 2 and 3, define the claimed invention of one of ordinary skill in the art and request that the rejection under 35 USC 112, second paragraph be withdrawn.


Applicants further submit that the rejection of claim 13 has been traversed by the present amendment. Specifically, in rejecting dependent claim 13, the Examiner stated that the term "improve" is a term of degree. The term "improve" has now been deleted and the claim has been changed to recite that the microstructured surface is configured to modify the surface energy of the fluid control film. As set out above, various embodiments of such modifications are set out in the specification at pages 19-21. In view of the amendment, Applicants request that the rejection of claim 13 be withdrawn.

Applicant submits that all of the pending claims are now in condition for allowance and requests that the Examiner provide the Applicant with a notice of allowance.

Respectfully submitted,

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